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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,913	04/06/2001	Atsumu Hirabayashi	NIT-276	7696

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EXAMINER	
MUTSCHLER, BRIAN L	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,913	HIRABAYASHI ET AL.	
	Examiner	Art Unit	
	Brian L. Mutschler	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 April 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it uses legal terminology such as "said wafery part" and "said passages". Correction is required. See MPEP § 608.01(b).

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The disclosure is objected to because of the following informalities:

a. The specification contains numerous grammatical informalities. For example, on page 1 at lines 22-23, the phrase "Every passages are" should be changed to --All of the passages are--, and on page 4 at line 17, the phrase "passages fulfilled with a solution" should be changed to --passages filled with a solution--. Other phrases, such as the sentence beginning at line 2 of page 20 are unclear due to the wording of the phrases. Applicant's assistance in correcting these and other informalities in the specification is kindly requested.

b. The first sentence in the paragraph beginning on page 11 at line 6 is misleading due to unclear language. A literal reading of the sentence implies that each of the buffer reservoirs has two electrodes, for a total of four electrodes. However, as shown in the drawings and explained in other parts of the specification, each reservoir has only a single electrode.

c. The phrase "electroosmosis flow", first appearing on page 12 at line 18, should be changed to --electroosmotic flow--.

Appropriate correction is required.

Claim Objections

4. Claims 4, 6, 7, and 12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The independent claims 1 and 9, from which claims 4 and 12 depend, each recite "a wafery part having passages." The limitation recited in claims 4 and 12, "wherein a plurality of said passages are provided in said wafery part" does not further limit the subject matter of the previous claims because the wafery part already has a plurality of passages by the independent claims use of the plural "passages".

Claims 6 and 7 recite limitations that pertain to the method of using the system. The intended use does not limit the structure of the system.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a wafery part and a passage, the disclosure does not reasonably provide enablement for having a wafery part interchangeable with the passage, as recited in claims 3 and 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 3 and 11 each recite the limitation "wherein said wafery part is interchangeable with said passage" in lines 2-3. If the passages are an integral part of the wafery parts as recited in claim 1, how can the wafery parts and the passages be interchangeable?

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the claims contain the phrase "wafery part". This phrase is indefinite because the word "wafery" uses a grammatical form that implies a meaning "resembling a wafer." Therefore, the term "wafery" is indefinite because it is not clear how the part resembles a wafer. A more appropriate phrase would be "wafer-shaped part" or simply the word "wafer".

Claim 1 recites the limitation "said sample solution" in line 9. There is insufficient antecedent basis for the singular form of "sample solution" in the claim. The same applies to dependent claims 2-8.

Claim 3 recites the phrase "said passage filled with a solution" in lines 2-3. First, there is insufficient antecedent basis for the singular form of "passage" in the claim. Second, which solution is filled within the passages? Since both sample solutions and buffer solutions are introduced in the independent claim, the solution should be positively identified. The same also occurs in claims 6 and 7.

Claim 5 recites the limitation "said passages" in line 2. This phrase is inconsistent with the "plurality of said passage" recited in claim 4, from which claim 5 depends, and "said plurality of passages" appearing in claim 6, which also depends from claim 4. Please use consistent language when referring to similar features. Also note the objection to claim 4 made above.

In addition to reciting only process limitations, claim 7 is indefinite because it is unclear how the intended use of displacing the wafery part cause the [sample(?)] solutions to flow sequentially. According to the disclosure, it is the application of a

voltage that cause the flow of the sample solution and not the displacement of the wafery part.

Claim 9 recites the limitation "said sample solution" in lines 9. There is insufficient antecedent basis for the singular form of "sample solutions" in the claim. The same applies to dependent claims 10-13.

Claim 11 recites the phrase "said passage filled with liquid sample" in lines 2-3. First, there is insufficient antecedent basis for the singular form of "passage" in the claim. Second, is the "liquid sample" the same as the "sample solutions" introduced in claim 9? If so, consistent language should be used throughout the claim to identify the same feature.

Claim 15 recites the phrase "the solution" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim. Is the solution the sample solution or the buffer solution? The same limitation also appears in claim 16 (lines 12-13), claim 17 (lines 13-14), and claim 19 (lines 13-14).

Claim 15 recites the limitation "solution having electrophoresis separated" in line 13. This limitation is not clear. The same phrase also appears in claim 16 at line 13. It was assumed that the phrase should mean that the sample is electrophoretically separated.

Claim 18 recites the limitation "the liquid sample solution" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim because the sample solution has not previously been identified as a liquid.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Simpson et al. (6,017,434).

Regarding claims 1, 9, and 14-16, Simpson et al. disclose a capillary electrophoresis device having a wafer part **438** having a plurality of passages, a body consisting of a bottom plate **446** and end pieces **458** and **459** (fig. 4; col. 12, line 38 to col. 13, line 5). Electrodes are included in the end pieces **458** and **459**, which also form buffer wells along with the bottom plate **446** (fig. 4; col. 12, line 56 to col. 13, line 5). The body has a configuration suitable to removably hold the wafer **438** and to move. Buffer solution is in contact with the migration lanes (col. 12, line 67 to col. 13, line 2).

Regarding claims 2, 8, and 10, the wafer part **438** is made of a dielectric material (col. 13, lines 65-67).

Regarding claims 3 and 11, since the wafer part **438** is a separate plate, other wafer parts with fluid-filled passages could be placed on the body, i.e., the wafer part is interchangeable.

Regarding claims 4 and 12, a plurality of passages is formed in the wafer part **438** (fig. 4).

Regarding claims 5 and 13, the passages are formed at even intervals within the wafer part **438** (fig. 4).

Regarding claims 6 and 7, the structural limitations recited in the instant claims are indistinguishable from the structure disclosed by Simpson et al.

Regarding claims 15 and 16, Simpson et al. further disclose an analyzer **100** for optically detecting and analyzing the separated sample (col. 10, lines 11-21).

Since Simpson et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

11. Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al. (U.S. Pat. No. 6,413,782).

Parce et al. disclose a moveable wafer holder **702** for holding a solution-filled wafer **704** (fig. 7; col. 30, line 54 to col. 31, line 33).

Since Parce et al. teach all of the limitations recited in the instant claim, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. (U.S. Pat. No. 6,017,434) in view of Fuchs et al. (U.S. Pat. No. 5,630,924) and Ramsey et al. (U.S. Pat. No. 6,110,343).

Regarding claims 17-19, Simpson et al. disclose a capillary electrophoresis device having a dielectric wafer part **438** having a plurality of evenly spaced passages, a body consisting of a bottom plate **446** and end pieces **458** and **459** (fig. 4; col. 12, line 38 to col. 13, line 5). Electrodes are included in the end pieces **458** and **459**, which also form buffer wells along with the bottom plate **446** (fig. 4; col. 12, line 56 to col. 13, line 5). The body has a configuration suitable to removably hold the wafer **438** and to move. Buffer solution is in contact with the migration lanes (col. 12, line 67 to col. 13, line 2). Simpson et al. further disclose an analyzer **100** for optically detecting and analyzing the separated sample (col. 10, lines 11-21).

The system of Simpson et al. differs from the instant invention because Simpson et al. do not disclose the following:

a. An ion source for ionizing the solution from the wafery part into gaseous ions, as recited in claims 17-19.

b. A mass spectrometer for performing mass analysis of the ions emitted from the ion source, as recited in claims 17-19.

Regarding the use of a mass spectrometer, Fuchs et al. disclose a chip-based capillary electrophoresis device and further teach that any conventional method may be

used in the apparatus, including optical detection or mass spectrometry (col. 22, lines 25-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the detector of Simpson et al. to use a mass spectrometer as taught by Fuchs et al. because Fuchs et al. teach that optical detection and mass spectrometry can equivalently be used as conventional methods to detect samples.

Regarding the use of an ion source to ionize the solution into gaseous ions, Ramsey et al. teach a chip-based capillary electrophoresis system using electrospray for generating gaseous ions for subsequent mass spectral analysis because no fragmentation occurs.

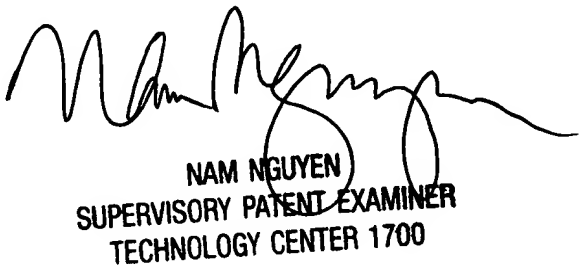
It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Simpson et al. to use an ion source to generate gaseous ions as taught by Ramsey et al. because electrospray does not cause fragmentation of the samples.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (703) 305-0180. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



NAM NGUYEN
SUPERVISORY PATENT EXAMINER
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December 9, 2003